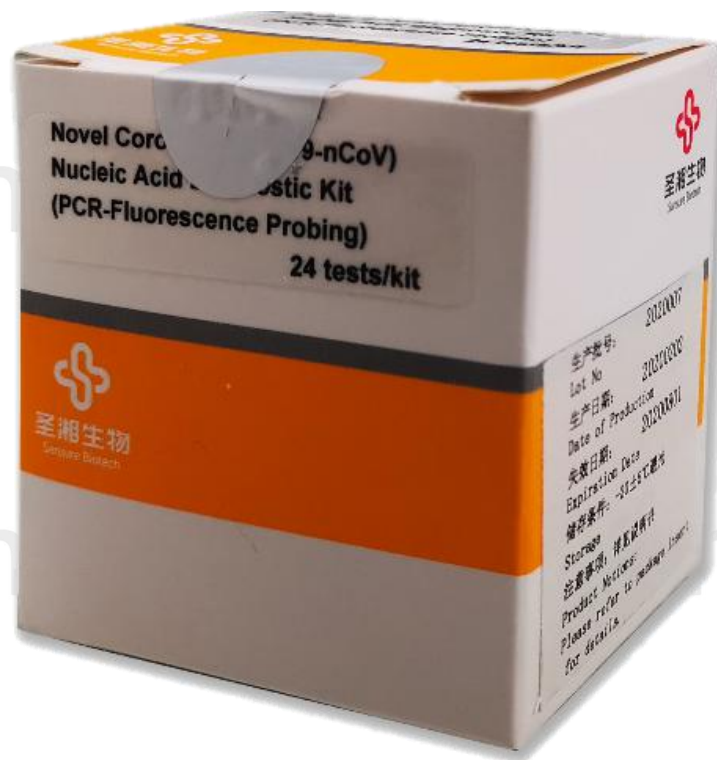


## Sansure Biotech

### Novel Coronavirus (2019-nCoV) nucleic acid detection overall solution recommendation



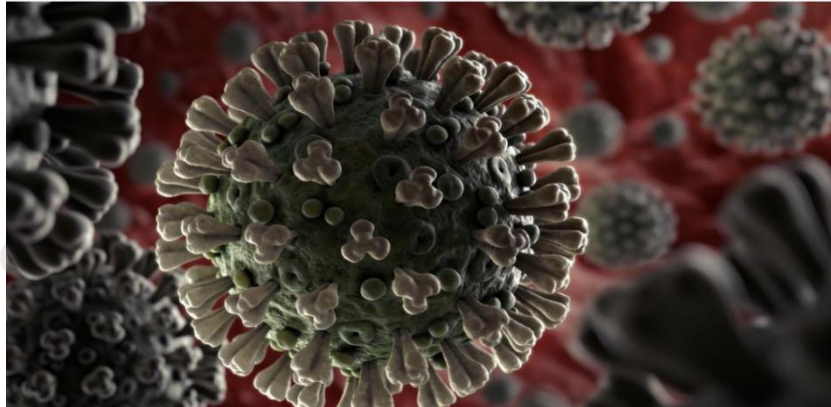
January 2020

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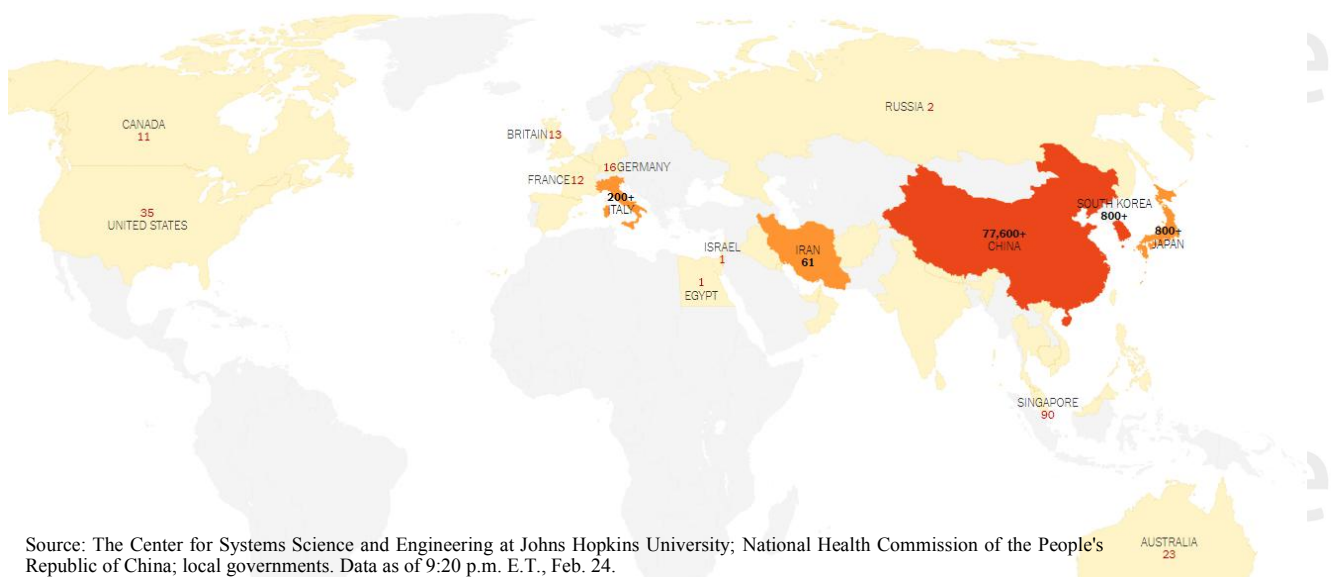
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## 1. Background of new coronavirus



Coronaviruses are single stranded RNA viruses with outer coat. They are the main pathogens that infect human and vertebrates and can cause a variety of acute and chronic diseases. So far, there are seven known human coronaviruses, including SARS and MERS. On 13 December, 2019, the seventh novel coronavirus disease causing the cluster of pneumonia outbreak in Wuhan which named as 2019 novel coronaviruses or “2019-nCoV”. And the World Health Organization(WHO) officially named the disease "COVID-19" in 11 February, 2020. The infected person may develop acute or severe respiratory disease, accompanied by fever, dry cough, shortness of breath and dyspnea. In severe cases, kidney failure and death may occurred.

## 2. Real Time Situation of COVID-19



As of 24<sup>th</sup>, February, 2020, there have been 79,331 confirmed cases, and 2,618 deaths of COVID-19, the deaths rate are nearly 3.3%, which have spread to 29 countries, including China, South of Korea, Italy, Japan, Singapore, Iran, Thailand, Malaysia, Germany, Viet Nam, Australia,

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United States of America, France, United Kingdom, United Arab Emirates, India, and so on, according to WHO novel coronavirus (COVID-19) situation. So far, the main affected country is China, but it has spread to lots of other countries around the world to a various degree.

### **3. Methodology recommended by WHO**

WHO was promulgated on 12<sup>th</sup>, January, 2020 novel coronavirus clinical diagnosis and treatment guidelines, and points out that for patients with suspected coronary virus, the sampling at the same time, the upper/lower airway by Real-Time PCR method to detect and diagnose patients at least once every 2-4 days testing, until two consecutive patients at least 24 hours between negative result, can be regarded as a clinical rehabilitation.

The use of nucleic acid detection methods can make rapid diagnosis, provide the basis for clinical diagnosis, treatment, and cure endpoints, and provide reliable data for epidemiological monitoring.

### **4. Sansure Biotech introduction**

Sansure Biotech is a high-tech company committed to bringing gene technology to the general public, which covers medical diagnostic reagents, instruments, and third-party medical testing services. At present, the company has become the global molecular diagnostic industry technology benchmark and the domestic molecular diagnostic industry leader.

As soon as the pneumonia epidemic of new coronavirus infection started in Wuhan, Sansure immediately established a technical research group to start developing relevant diagnostics solutions, and successfully developed a 2019 novel coronavirus nucleic acid detection reagent on 14 January, 2020. Sansure's 2019-nCoV nucleic acid detection kit was approved by the Chinese National Medical Products Administration and obtained a CFDA certification.

As of February 16, Sansure has sold over 5 million tests of 2019-nCoV detection kits, with a market share of over 50% in China, and has been used for quarantine in more than 10 countries, such as Ethiopia, Thailand, Malaysia, Laos, Dubai, Cambodia and so on.

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## 5. Sansure solution

### Solution 1: iPonatic Quick Screening Solution (Based on One-tube technology)



#### Advantages:

1.The instrument integrates the rapid nucleic acid extraction with amplification system, completing nucleic acid extraction, PCR amplification and result analysis by one step with high accuracy.

2.Simple operation, the whole reaction time from sample to result outputed are less than 40 minutes.

3.The whole instrument weight is less than 10kg, which is compact and portable, it can use as testing and monitoring the 2019-nCoV on spot.

### Solution 2: Fully Automated Nucleic Acid Screening Solution



#### Advantage:

1.Fully automated detection to avoid manual errors, avoid exposure risks, and avoid contamination.

2.High-throughput: Natch CS fully automatic nucleic acid extraction instrument with one-tube method can process 96 samples almost 30 minutes, real-time PCR can amplify 96 samples at 100 minutes, sample processing can reach >1,000 samples/day;

3.It can also applied with magenetic beads method can process 96 samples almost 90 minutes, real-time PCR can amplify 96 samples at 100 minutes(magenetic beads method can matching with various specimens).

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### **Solution 3: No extraction solution based on one-tube fast /Magnetic Beads**

#### **Method**



#### **Advantage(One-tube Method):**

- 1.Simple operation, no heating, no need tube changing, simple sample preparation;
- 2.Rapid detection of new coronavirus with real-time PCR instrument;
- 3.Magnetic Beads Method available to lots of specimens, such as swab, sputum,alveolar lavage fluid, pleural fluid sample, faeces and so on;

### **6. Introduction of Sansure 2019-nCoV detection kit**

The Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic kit based on the Sansure's unique "RNA one-step" technology, it can be applied to different application scenarios, and can provide the quick, simple and high-throughput nucleic acid detection scheme for epidemic prevention and control; the operation process is extremely simple, and the biological safety is high. After a little training, the laboratory specialist can have the ability to do nucleic acid detection, which can quickly help the laboratory to establish the detection ability. For magnetic beads method, it also with simple operation and can apply to various specimens, such as swab, sputum, alveolar lavage fluid, pleural fluid sample, faeces and so on.

The kit combines with the fully-automatic nucleic acid extraction system independently developed by Sansure and amplification by the common PCR instrument, the high-throughput detection can be realized with one person, one machine and one day detection sample size of more than 1000.

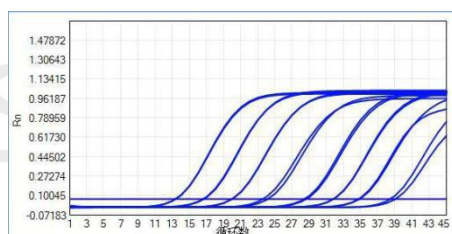
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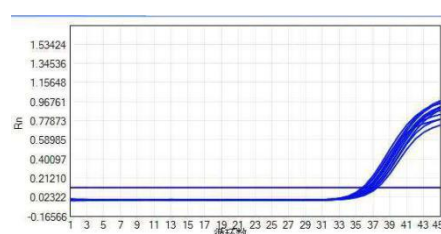
### Product technical parameters:

Product name	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic kit(PCR-Fluorescence Probing)
Extraction method	One step method/Magnetic bead method
Target	FAM for ORF1ab gene, HEX for internal control, ROX for N gene.
Internal Control	Endogenous housekeeping gene internal standard
Sensitivity	200 copies/mL
Nucleic acid lysis	Sample lysis at room temperature.
Sample type	Alveolar lavage fluid, throat swab, sputum
Packing Specification	24 tests/kit
Compatible Instrumen	ABI 7500/SLAN-96P/ABI Q5/Roche z480
Registration Certificate No.	CFDA certified No.20203400064

### Product performance:



Linear range:  $10^2$ - $10^9$  copies/ml



Sensitivity: 200 copies/ml

## 7. Introduction of iPonatic

iPonatic is the latest portable POCT developed by Sansure Biotech Inc., based on Sansure's core technology---one-step nucleic acid free extraction technology, and with a rapid nucleic acid detection system, one-stop complete sample lysis, nucleic acid extraction, PCR amplification and result analysis, the whole process from the sample in to the result out, less than 40 minutes.

Simple operation, no need professional operation, a person who get general training can start the operation, in the process of operation only need to add samples in the reagent strip, and then the reagent strip can be put into the instrument. The instrument can automatically execute the

experimental items and analyze the result.

It can accurately detect a variety of pathogens and gene targets, and has a wide range of detection projects to meet the needs of customers. Extensive application scene, without the need for professional laboratory, really realized the full scene coverage.

#### Product specification:

Ramp Rate	Max 8℃ (50-100℃)			
Cooling Rate	Max 2℃ (50-100℃)			
Heating/Cooling Technology	Liquid metal coated ceramic heating/Air bath cooling			
Temperature Control	Independent heating module / Independent module control			
Temperature Accuracy	±0.3℃ (50℃~100℃)			
Temperature Range	±5℃~99℃			
Sample Volume	25ul/50ul			
Interface	RS232			
Power	DC24V,30W			
Light Source	LED (maintenance-free)			
Detector	High sensitivity photoelectric sensor			
Detection Mode	Real-time dynamic monitoring			
Channels	4			
Excitation	Channel 1	Channel 2	Channel 3	Channel 4
	470nm	525nm	580nm	635nm
Dyes	FAM	VIC	ROX	CY5
Sensitivity	1 copy			